OFFICE OF THE ATTORNEY GENERAL OF TEXAS
AUSTIN

GROVER SELLERS
ATTORNEY GENERAL

Honorable Walter Cousins, Jr., Secretary
Texas Board of Pharmacy
911 Southland Life Annex Building
Dallas 1, Texas

Opinion No. O-7381

Re: Interpretation of Article 4542a, Section 8, V. A. C. S., relative to right of non-registered person removing labels from original manufacturer's package, replacing it with instructions of physician for usage

Dear Sir:

Your letter of August 26, 1946, requesting an opinion from this office relative to the above subject reads as follows:

"We have been confronted with the necessity of an interpretation of Article 4542A, Section 8, V.A.C.S., the Texas Pharmacy Law relative to the right of a non-registered person removing the label from the original manufacturer's package of a vitamin product replacing it with the instructions of a physician for usage.

"It is the contention of the distributor of this preparation that his removal of the original label upon the instructions of a physician does not change the original package. While it is our belief that such re-labeling is restricted to pharmacists registered under provisions of the Pharmacy Law."

Introductory to an interpretation of the above cited Section 8, it is noted that this section is one of seventeen comprising Article 4542a and that this article is included in Vernon's Annotated Civil Statutes as "Chapter Eight-Pharmacy" in the Public Health title number 71. This Article 4542a is comprehensive regarding

the regulation of the practice of Pharmacy and was revised and re-enacted by the 48th Legislature in 1943. It is significant that the emergency clause of the 1943 act recites the reason for the revision to be that "the present Pharmacy Law is inadequate and endangers the public health and the public welfare of this state." Specifically, Section 8 as it was amended in 1943 reads as follows:

> "Sec. 8. It shall be unlawful for any person who is not a registered pharmacist under the provisions of this Act to compound, mix, manufacture, combine, prepare, label, sell or distribute at retail or wholesale any drugs or medicines, except in original packages. Provided that all persons now registered as pharmacists in this state shall have all the rights granted to pharmacists under this Act. Provided, however, that nothing in this Act shall apply to or interfere with any licensed practitioner of medicine, dentistry or chiropody, who is duly registered as such by his respective State Board of Examiners of this state, who shall supply his or her patients, as a physician, dentist or chiropodist, and by them employed as such, with such remedies as he or she may desire and who does not keep a pharmacy, open shop or drug store, advertised or otherwise, for the retailing of medicines or poisons; and provided, further, that nothing contained in this Act shall be construed to prevent the personal administration of drugs and medicines carried by any physician, surgeon, dentist, chiropodist or veterinarian licensed by his respective Board of Examiners of this state, in order to supply the immediate needs of his patients; nor to prevent the sale by persons, firms, joint stock companies, partnerships or corporations, other than registered pharmacists, of patent or proprietary medicines, or remedies and medicaments generally in use and which are harmless if used according to instructions as contained upon the printed label; and insecticides and fungicides and chemicals used in the arts, when properly labeled; nor insecticides or fungicides that are mixed or compounded for purely agricultural purposes."

This is a clear and unambiguous provision broadly prohibiting anyone who is not a registered pharmacist under the Act or who is not specifically excepted thereby from tampering with drugs and medicines. The plain intent of this section, as well as other provisions of the Act, is that the public shall be protected from ignorance, irresponsibility, or carelessness in the purchase of drugs and medicines through strict regulation. By the terms

of these provisions, the handling of drugs and medicines (for human consumption) is permitted only under three clear requirements, namely: (1) the person handling them must be a registered pharmacist under the Act; (2) the person handling them must be a physician, dentist, chiropodist, etc. licensed to practice by his respective Board of Examiners; or (3) the drugs or medicines must be sold or distributed in their original packages which bear a printed label giving instructions for their use. Necessarily, the preparation, packaging, and labeling of the drugs and medicines in this last requirement would be in conformity with Federal and State food and drug laws and regulations. A discussion of such laws and regulations, however, is not here necessary.

In the case submitted, a person who is neither a registered pharmacist nor a licensed physician under the first two requirements above noted, removes the printed label from a package of vitamins and replaces it with a physician's directions for its use. A pertinent fact, in addition to those in the above letter, has also been supplied, namely, that the physician is not present when this labeling or re-labeling occurs. It is also clear from your letters that the re-labeled packages are not returned to the doctor but are sold or distributed to the consumer.

This case is clearly in violation of the provisions of Section 8, supra, unless, as it is contended by the distributor, it is exempted therefrom by the exception pertaining to original packages contained in the first sentence or, more specifically, unless this exception as to original packages applies to the labeling as well as to the selling and distributing of drugs and medicines. Patently, this exception refers only to the phrase "sell or distribute at retail or wholesale", and operates to permit persons not registered to sell drugs in their original packages. Obviously, the exception could not conceivably modify or affect other acts prohibited as it would be impossible "to compound, mix, manufacture, combine, prepare," drugs without breaking the original package. Neither can it refer to the remaining item "label" included in this group. On the contrary, in the sale of drugs to the public, individual labels showing a doctor's directions are a part of preparation and to "label" in this manner is, in part at least, to "prepare." This can be reconciled with the definitions given in Section 20 of Article 4542a where a "pharmacist" is said to be one who "compounds, prepares, or dispenses" while

a "manufacturer" is one who, among other things, "labels, packages or manufactures". Parenthetically, it may be noted that Section 17 of Article 4542a requires a manufacturer to secure a permit for each factory and to register the name of the pharmacist or "pharmaceutical chemist" employed at such factory.

That the exception made of original packages does not apply to the prohibited act of labeling can be further reconciled (and clarified, if necessary) with other provisions of the Section. In the above quoted Section 8 it is provided that the prohibition shall not prevent "the sale . . . of patent or proprietary medicines, or remedies and medicaments generally in use and which are harmless if used according to the instructions contained on the printed label". Thus the "original packages" excepted are those containing directions which are harmless if used in accordance with "the printed label", and the two exceptions are consistent. The label is an essential part of the original package.

The term "original package" has been used in various statutes and has been generally defined by the authorities in the light of the context in which it is used (See 30 Words & Phrases, pp. 309-316). In commerce the term is said to mean not the individual box or bottle but the larger container in which these are packed and shipped, and this meaning has been applied to medicine in bottles (State vs. Parsons, 27 SW 1102). But applied to the instant case, such a meaning would exclude even a "properly labeled" bottle from the exception, and in as much as the provision (Section 8) specifically includes retail sales, the definition given in a later case appears to be more applicable. In Kentucky Board of Pharmacy vs. Cassidy (74 SW 730) the court, in construing a similar provision prohibiting a person not a registered pharmacist from selling or dispensing drugs or medicines "except proprietary or patent medicines in original packages", defined the term "original packages" as follows:

> "The term 'original package,' as applicable to the sale of patent and proprietary medicines, means--and is so understood by all persons--the small individual package or bottle as prepared for retail, and not the large box or package in which the smaller packages may have been shipped by the manufacturer, and is so used in St. 1899, c. 85, § 2631, authorizing the sale of patent medicines in original packages." (Emphasis added)

It will be noted in the above that the small individual package or bottle was one "prepared for retail" and patently a package so prepared would bear a printed label. Any other understanding of the term and particularly the one contended for in this case might have the absurd effect of making the enforcement of the statute depend on proving that the cork was removed. There can be no original package as used in this Act until a container has been labeled. Labeling being necessary to the existence of an original package, the exception cannot refer to it.

The above can be further substantiated by comparing the provisions of the above quoted Section 8 with those of this section prior to its revision in 1943. Under the prior provision the handling of drugs by one under the direct supervision of a registered pharmacist was excepted from the prohibition, but this was eliminated in the amendment. The prohibition of the prior law named the acts of compounding, mixing, and manufacturing, and in the amendment there was specifically added the acts of combining, preparing, and labeling. Also under the old law it was unlawful to "sell or distribute at retail to the consumer any drugs or medicines, except in original packages" while the new law was made to include wholesale selling and distribution, "except in original packages". It is significant also that in the exception pertaining to patent and proprietary medicines in the prior provision the sale of "original packages" was specifically permitted "when properly labeled." Thus the provision (Section 8) was revised to make it more adequate to the protection of the public.

In the 1943 enactment the penal provisions of the act were also amended. Consistently with the revision of Section 8, in Section 17 of the Act (now codified in Vernon's Annotated Penal Code as Article 758a), it was provided:

> "'Any person not being licensed as a pharmacist who shall compound, mix, blend, dispense, prepare or sell at retail any drugs, medicines, poisons or pharmaceutical preparations upon a physician's prescription, or otherwise, and whoever, being the manager or owner of the drug store, pharmacy or factory, or other place of business, shall manufacture, or permit anyone not licensed as a pharmacist to compound, mix, blend, dispense any drugs, medicines, poisons or pharmaceutical preparations, on

physician's prescription, contrary to any of the provisions of this Act, shall be subject to the penalties of this Act."

This provision, however, is mentioned only to further illustrate the manifest meaning and intent of Section 8, supra, of which the request presented asks for an interpretation, and a discussion of whether the instant case would constitute a violation of the penal provisions is pretermitted. Clearly, it is unlawful for anyone not registered to "prepare or sell at retail" drugs, medicines, or preparations "upon a physician's prescription or otherwise."

Concerning the remedies and procedures for violation, it is noted that the Board of Pharmacy is given the power (Article 4542a, Section 5) to "institute an action in its own name to enjoin violation of any of the provisions of this Act," and that such action shall be in addition to any other authorized by law.

It is not necessary to elaborate on the proposition that vitamins in the instant case are "drugs or medicines" within the meaning of the statute. There are many preparations, of course, which under a broad generic definition of the term "food" might be classified as such, and in some instances classification would depend on the specific use of the preparation. Generally, vitamins are drugs or medicines, and in the instant case the very contention as to their sale in original packages admits this classification.

The foregoing considered, it is concluded that any sale of drugs after the printed label has been removed is not the sale of original packages excepted in the statute and that the contention of the distributor in the case presented is without merit.

Accordingly, you are advised that in the opinion of this office, the facts submitted would constitute a violation of the provision of the Section 8 cited.

Yours very truly

ATTORNEY GENERAL OF TEXAS

APPROVED OCT 24, 1946

Harry Lee Foster

FYRST ASSISTANT
ATTORNEY GENERAL

By Jackson Littleton
Jackson Littleton
Assistant

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